INITIAL REVIEW ENGINEERING REPORT [redacted]
PMN: 20-0025

Post Scoping Ready v1 1/14/2020
ENGINEER: El-Zoobi \ MLS \ CMF
PV (kg/yr): 5,000,000 YX

Revision Notes / Assessment Overview: Post Scoping Ready v1 (01/14/20): The following changes were made: (1) the names and addresses of the manufacturing and processing sites were added. (2) the media of release pertaining to releases from cleaning equipment and drums at the manufacturing and processing sites were changed from uncertain to incineration because the submitter has a toll manufacturing and processing agreement with the manufacturing and processing sites, respectively and these agreements include a provision for incineration of these waste streams. Another change made to the Scoping Ready report is that the batch volumes were revised to account for the contact report.

SUBMITTER: Biosynthetic Technologies

USE: Int[redacted]: Lubricant for motor oils.
Same as [redacted].
Analogue[redacted]se): [redacted]
Patents (same use): Non[redacted]

OTHER USES: Analogues (other use): [redacted]: Solid emollient in personal care preparat[redacted]ure of polycarbon[redacted]: Co-emulsifier in cosmetics. [redacted]ther use): None found.
Patents (other use): 6 references found, 4 of which are patents. All [redacted]rmulations. CA 135:362599 [redacted]; CA 133:79041 [redacted]; CA 90:16[redacted]A 86:95870 [redacted]

MSDS: Yes Label: No

Gen Eqpt: Engineering controls: Good general ventilation should be sufficient to control worker exposure to airborne contaminants. // Eye/face: Safety eyewear complying with an approved standard should be used when a risk
assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with sideshields. // Hand: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. // Body: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. // Other skin: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respirator: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Health Effects: No known significant effects or critical hazards.
TLV/PEL:

CRSS (12/02/2019):
Chemical Name: Octadecanoic acid, 12-(acetoxy)-, 2-ethylhexyl ester

S-H20: 1E-06 g/L @
VP: 1.0E-6 torr @
MW: 454.74 0.00%<500 0.00%<1000
Physical State and Misc CRSS Info:
Neat: Liquid Mfg: Liquid Proc/Form: Solution: 35% PMN substance in motor oil formulation, or Solution: 38% PMN substance in motor oil formulation End Use: Solution: 35% PMN substance in motor oil formulation, or Solution: 38% PMN substance in motor oil formulation . Submitted data: An FT-IR, C13 NMR, 1H NMR and UV-vis spectra were provided in the submission. A gas chromatogram was also included.
Submitted properties: Liquid; Flash point = 204 °C (ASTM D93); Density = 0.9065 g/cm3 (ASTM D4052); Freezing point = -15 °C (ASTM D5972); VP = 1.3 torr at 26.8 °C (ASTM D2879) This value seems too high to be plausible, likely due to residual feedstocks; BP = 401-591 °C (ASTM D6417); log P > 7.6 (OECD 117); Direct measurements of the water solubility by OECD test guideline 105 were not possible due to the surfactant properties of the test item; Viscosity (Kinematic, 40 °C) = 23.2 cSt (L-19-0227); Pour point = -21 °C (L-19-0227).
Estimated data: (EPI, MP = -15 °C, BP = 401 °C, SMILES = C(C)CCCCC(OC(=O)C)CCCCCCCCCCC(=O)OCC(CCCC)CC): BP = 448.84 °C; VP = 7.86E-06 torr; WS = 2.011E-06 mg/L; log P = 11.06.
Estimated Data (STN/ACD Labs): BP = 449.4 °C; VP = 2.86E-08 torr; WS = 0.000017 g/L; log P = 10.74.

Consumer Use: Yes
SAT (concerns) :
Related [redacted] Misc SAT Info:
Same as Analogue [redacted].
Migration to groundwater: null null
PBT rating: P1B1T2
Health: Dermal, Drinking Water, Inhalation
Eco: 1 No releases to Water

OCCUPATIONAL EXPOSURE RATING: 1C

NOTES & KEY ASSUMPTIONS:
Occupational exposure and environmental releases were estimated using ChemSTEER v3.2 (5/12/2016). Input to ChemSTEER tool includes information from: the PMN submission, physical / chemical properties, relevant past cases, and the Sept 2000 Lube Oil Additives GS. Note, SAT report was not available as of 8/26, [redacted] ent with [redacted]; other referenced past cases did not assess MFG) and loading per the submissio [redacted] IRER assesses dermal exposure during loading (consistent with [redacted]). // PROC: Releases from container and equipment cleaning wer [redacted] ed (consistent with all past cases). Dermal exposure from unloading raw material was assessed (consistent with all past cases). // USE: The Sept 2000 Lube Oil GS was referenced for information (consistent with all past cases). Releases were assessed per the GS for incineration of disposed oil and landfill [redacted] from landfilling, and road oiling (consistent with [redacted] and [redacted]). Releases from cleaning or disposal of containe [redacted] ining t was assessed (consistent with all past cases). Dermal exposure from handling lubricant was assessed (consistent with all past cases).

POLLUTION PREVENTION CONSIDERATIONS:

Estolides are a family of chemical compounds most simply defined as oligomers of fatty acids. Such structures have existed in nature for millions of years, with analogous fatty acid polyesters making up the waxy coating on leaves of herbaceous plants. These lipophilic structures, referred to as cutin, help reduce water loss and protect plants from pathogenic fungi and bacteria. With knowledge of their preexistence in nature, its perhaps unsurprising that estolides are environmentally acceptable materials, readily biodegrading in the environment, non-toxic, and not bioaccumulative. In the 1990s, scientists at the USDA developed these materials in a laboratory setting, discovering their potential for use as synthetic lubricants. Not only did estolides lessen the impact on the environment, they also outperformed conventional base oils in a number of categories. From a physiochemical perspective, estolides have excellent performance in the areas of viscosity index, volatility, thermal conductivity, heat capacity, oxidative stability, hydrolytic stability, solvency, wear, and shear stability. In motor oil formulations, estolides have proven to increase engine cleanliness, reduce wear, and potentially improve fuel economy. Estolides have further been evaluated for use in metalworking fluids, greases,
gear oils, stern tube oils, compressor oils, drilling fluids, hydraulic fluids, dielectric fluids, heat transfer fluids, and even as rubber additives and plasticizers. Benefits of the estolide technology continue to be discovered as formulators investigate new uses for these novel ingredients. Estolides are now being commercialized as replacements for petroleum oils. These estolide oil are known for their environmental and performance benefits. Estolides were used to develop one of the first American Petroleum Institute (API) approved motor oils. BT4 is the trade name for one of these oils. It is a low viscosity estolide oil that can be used in many applications but will be used primarily to replace petroleum in the next generation of motor oils.
Due to their environmental profiles, lubricant performance, and synthetic flexibility, estolides are rapidly gaining traction as an alternative to conventional, petroleum-derived, lubricant base oils.

EXPOSURE-BASED REVIEW: Yes (1 criteria met)
1) # of workers exposed: 438 >1000? No
2) >100 workers with >10 mg/day inhalation exposure: No
3) (a) >100 workers w/1-10 mg/day inh. exp. & >100 days/yr: No
(b) Routine Dermal Cont: >250 workers & >100 days/yr: Yes

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MFG: Batch

Number of Sites/ Location: 1

WEYLCHEM US INC ELGIN SC 29045-9262

Days/yr: 250

Basis: Submission identifies 1 site. Per CRSS, PMN is manufactured in neat form, 100% PMN. RAD assumes 250 days/yr. ChemSTEER calculates 20,000 kg PMN/bt.

Process Description: [redacted]

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium. The submitter states that the manufacturing site is a toll manufacturing facility. The following NPDES information was provided by the submitter for the manufacturing site:
WeylChem
2114 LARRY JEFFERS ROAD
Elgin, SC
NPDES No. SC0039870

Incineration
Conservative: 4.0E+2 kg/site-day over 250 days/yr from 1 site
or 1.0E+5 kg/site-yr from 1 site or 1.0E+5 kg/yr-all sites
to: Off-site Incineration (submission)
from: Equipment Cleaning Losses of Liquids from Multiple Vessels
basis: EPA/OPPT Multiple Process Vessel Residual Model, CEB standard 2% residual. Submission estimates a release of 0.5 kg/bt from equipment cleaning to off-site incineration. However, the submission does not include batch parameters so RAD could not estimate the loss fraction from this estimate. RAD assessed this release with standard model to the release to incineration becasue manufacturing would occur pursuant to a toll manufacturing agreement between the submitter and the toll manufacturing site that includes a provision for release to incineration of this waste steam according to the submission.

Incineration
Output 2: 5.0E-2 kg/site-day over 250 days/yr from 1 site
or 1.2E+1 kg/site-yr from 1 site or 1.2E+1 kg/yr-all sites
to: Off-Site Incineration (submission)
from: Loading Liquid Product into Totes
basis: User-Defined Loss Rate Model. Submission estimates a release of 0.05 kg/bt from loading product released to off-site incineration. However, the submission does not include batch parameters so RAD assumed this is a daily release and assesses the release to incineration becasue manufacturing would occur pursuant to a toll manufacturing agreement between the submitter and the toll manufacturer that includes a provision for release to incineration of this waste steam according to the submission.

RELEASE TOTAL
1.0E+5 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: 3
Basis:

Inhalation:

Volatilization is negligible (VP < 0.001 torr) and the formation of respirable PMN is not expected during this operation.

Dermal:

Exposure to Liquid at 100.00% concentration
High End:
> Potential Dose Rate: 2.2E+3 mg/day over 250 days/yr
> Lifetime Average Daily Dose: 9.9E+0 mg/kg-day over 250 days/yr
> Average Daily Dose: 1.9E+1 mg/kg-day over 250 days/yr
> Acute Potential Dose: 2.8E+1 mg/kg-day over 250 days/yr
Number of workers (all sites) with dermal exposure: 3
Basis: Loading Liquid Product into Totes; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

INITIAL REVIEW ENGINEERING REPORT [redacted]

PMN: 20-0025

PROC: Blending into finished lubricant

Number of Sites/ Location: 1

ROYAL PURPLE PORTER TX 77365

Days/yr: 333

Basis: Submission states that PMN is formulated to 35% or 38%, there are 60 operator exposure days per year, and that there is 1 processing site. RAD assesses with a concentration of 38% as conservative. The technical contact stated that the batch parameters of the processing site assume a PV equal to the maximum PV for the first 12 months (300,000 kg/yr). With 60 batches/yr, this equals 5,000 kg/batch. Scaling up to the maximum 12 month PV, batches/yr = 1000 (333 Operating days with 3 lines running).

Process Description: LVE unloaded (liquid, 100%) --> charged to blending tank --> blended into finished lubricant packages (liquid, 35-38%) --> bottle filling--> shipped to retail outlets for consumer and commercial use (submission and CRSS)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Incineration
Conservative: 3.0E+2 kg/site-day over 1 day/yr from 1 site
or 3.0E+2 kg/site-yr from 1 site or 3.0E+2 kg/yr-all sites
to: Uncertain
from: Equipment Cleaning Losses of Liquids from a Multiple Vessels

basis: EPA/OPPT Multiple Process Vessel Residual Model. Submission does not estimate this release, and it is non-submitter controlled site. RAD uses standard EPA/OPPT Multiple Process Vessel Residual Model, CEB standard 2% residual RAD assessed this release with standard model to incineration becasue processing would occur pursuant to a toll processing agreement between the submitter and the toll processing site that includes a provision for release to incineration of this waste steam according to the submission. Note that the 2000 Lube Oil GS indicates release is to water and 2016 Draft Lube Oil ESD indicates release is to incineration or landfill). RAD assesses 1 day of release for equipment maintenance in accordance with the submission.

Incineration
High End: 1.5E+2 kg/site-day over 48 days/yr from 1 site
or 7.2E+3 kg/site-yr from 1 site or 7.2E+3 kg/yr-all sites
to: Incineration (per submission)
from: Cleaning Liquid Residuals from Drums Used to Transport the Raw Material

basis: EPA/OPPT Drum Residual Model, CEB standard 3% residual. RAD assessed this release to incineration because processing would occur pursuant to an agreement between the submitter and the toll processing site that includes a provision for release to incineration of this waste steam according to the submission and contact report.

RELEASE TOTAL
7.5E+3 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: 15
Basis:

Inhalation:

negligible (VP < 0.001 torr); formation of respirable vapor or mist of PMN is not expected from this operation

Dermal:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Liquid at 100.00% concentration

High End:

> Potential Dose Rate: 2.2E+3 mg/day over 250 days/yr

> Lifetime Average Daily Dose: 9.9E+0 mg/kg-day over 250 days/yr

> Average Daily Dose: 1.9E+1 mg/kg-day over 250 days/yr

> Acute Potential Dose: 2.8E+1 mg/kg-day over 250 days/yr

Number of workers (all sites) with dermal exposure: 15

Basis: Unloading Liquid Raw Material from Drums; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

INITIAL REVIEW ENGINEERING REPORT [redacted]

PMN: 20-0025

USE: Commercial Lube Oil (75% PV)

Number of Sites/ Location: 140

unknown site(s)

Days/yr: 250

Basis: Nsites = [(78,766 gen. auto sites + 7,697 pure lube sites) * (5,000,000 kg/yr * 2.2 lb/kg * 0.133 gal/lb)/(0.365 [weighted avg b/w 0.35 and 0.38] * 2,472 Mgal/yr * 1,000,000 gal/Mgal) = 140 sites. GS indicates 250 days/yr for general automotive sites. RAD assumes 250 days/yr. CS calculates 107 kg LVE /st-day.

Process Description: Lubricant fluid shipped from warehouse and unloaded (liquid, 35 or 38%) --> Manual or automated transfers of fluid containing LVE into engines and transmissions (per past cases and Lube Oil GS). // Note submission indicates 25% is designated for consumer use. This operation assesses the 75% of the PV that is used for commercial applications.

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Water or Incineration or Landfill
High End: 6.4E-1 kg/site-day over 250 days/yr from 140 sites
or 1.6E+2 kg/site-yr from 140 sites or 2.3E+4 kg/yr-all sites
to: uncertain
from: Cleaning Liquid Residuals from Small Containers Used to Transport the Raw Material
basis: EPA/OPPT Small Container Residual Model, CEB standard 0.6% residual. Submission does not estimate releases from container cleaning or disposal. RAD assesses with standard model to uncertain media.

Incineration
Output 2: 8.9E+1 kg/site-day over 250 days/yr from 140 sites
or 2.2E+4 kg/site-yr from 140 sites or 3.1E+6 kg/yr-all sites
to: Incineration (per GS)
from: Incineration of Disposed Oil (GS)
basis: User-Defined Loss Rate Model. Submission does not provide release esitmates for this operation. GS estimates 83.2% of used automotive oils are burned (incinerated).

Other
Output 2: 8.2E+0 kg/site-day over 250 days/yr from 140 sites
or 2.1E+3 kg/site-yr from 140 sites or 2.9E+5 kg/yr-all sites
to: Land and/or landfill (per GS)
from: Landfill, Dumping, or Road Oiling (GS)
basis: User-Defined Loss Rate Model. Submission does not provide release esitmates for this operation. Per the Sept 2000 Lube Oil GS, 7.7% of spent lube oil is released to land (dumping, landfilling, and road oiling).

RELEASE TOTAL
3.4E+6 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: 420
Basis:

Inhalation:

negligible (VP < 0.001 torr); formation of respirable vapor or mist of PMN is not expected from this operation

Dermal:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Liquid at 35.00% concentration
High End:
> Potential Dose Rate: 7.9E+2 mg/day over 250 days/yr
> Lifetime Average Daily Dose: 3.5E+0 mg/kg-day over 250 days/yr
> Average Daily Dose: 6.7E+0 mg/kg-day over 250 days/yr
> Acute Potential Dose: 9.8E+0 mg/kg-day over 250 days/yr
Number of workers (all sites) with dermal exposure: 210
Basis: Unloading Liquid Raw Material from Small Containers - 35%; EPA/OPPT 2-Hand Dermal Contact with Liquids Model. Note that half of the PV is used at 35% and the other half at 38% PMN. RAD assesses workers at half the sites eposed to 35% PMN in this operation.

Exposure to Liquid at 38.00% concentration
High End:
> Potential Dose Rate: 8.5E+2 mg/day over 250 days/yr
> Lifetime Average Daily Dose: 4.8E+0 mg/kg-day over 250 days/yr
> Average Daily Dose: 8.4E+0 mg/kg-day over 250 days/yr
> Acute Potential Dose: 1.2E+1 mg/kg-day over 250 days/yr
Number of workers (all sites) with dermal exposure: 210
Basis: Unloading Liquid Raw Material from Small Containers - 38%; EPA/OPPT 2-Hand Dermal Contact with Liquids Model. Note that half of the PV is used at 35% and the other half at 38% PMN. RAD assesses workers at half the sites eposed to 38% PMN in this operation.